

# Notice of Allowability

Application No.

09/870,729

Applicant(s)

SHUBER, ANTHONY P.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/7/2004.
2. ☒ The allowed claim(s) is/are claims 28-39 (claims 1-12).
3. ☒ The drawings filed on 30 May 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### RESEASONS FOR ALLOWANCE

The applicant's Response (filed 1/7/2004) to the Office action has been entered, claims 28-39 are pending.

1. The following is an examiner's statement of reasons for allowance:

Concerning claims 28-39, no prior art has been found teaching or suggesting the method for detecting cross-sample contamination in an amplification reaction comprising conducting an amplification reaction in a first nucleic acid sample using at least one chimeric primer comprising a first portion that hybridizes to a portion of a target nucleic acid and a second, contamination detection portion that does not hybridize with the target nucleic acid, conducting a subsequent control amplification reaction in a second nucleic acid sample using at least one primer to specifically amplify the contamination detection portion of the chimeric primer and determining whether the second sample has been contaminated by an amplicon from the first sample by determining whether the control reaction produces an amplicon.

The closest prior art is the reference of Shuldiner et al. (WO 91/15601). Shuldiner et al. disclose a method, which can be used to distinguish RNA in the sample from contaminating DNA (See pg. 6, lines 23-27). The method applies a first oligonucleotide primer designated d<sub>20</sub>-t<sub>21</sub> which comprises the 3' end, a nucleotide sequence complementary to the 3' end of the RNA and the 5' end, a unique random nucleotide sequence or tag which does not hybridize to the RNA sequence within the sample. The distinction between DNA generated from the RNA-template and possible contaminating DNA can be detected (See pg. 7, lines 27-29), but Shuldiner et al. do not disclose determining whether the second sample has been contaminated by an amplicon from the first sample by determining whether the control reaction produces an amplicon.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

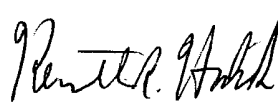
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung

JT  
April 6, 2004

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

4/8/04